

Please replace the paragraph beginning at page 1, line 5,  
with the following rewritten paragraph:

Q1  
--The present invention relates to percutaneously delivered  
stent-grafts for repairing abdominal aortic aneurysms.--

Please replace the paragraph beginning at page 5, line 21,  
with the following rewritten paragraph:

Q2  
--In accordance with the present invention there is  
provided a hollow substantially cylindrical radially  
expandable stent having proximal and distal open ends and a  
longitudinal axis extending therebetween. The stent is for  
deployment within a human body vessel, and is particularly  
useful in the manufacture of stent-grafts. The stent  
includes a plurality of hoops comprising a plurality of  
interconnected struts. The stent has a proximal end hoop  
and a distal end hoop wherein the distal end hoop and the  
proximal end hoop have greater radial and longitudinal  
strength than the hoops therebetween. The stent further  
includes a plurality of sinusoidal rings connecting  
adjacent hoops to one another.--

Please replace the paragraph beginning at page 8, line 23,  
with the following rewritten paragraph:

Q3  
--Referring now to the drawings wherein like numerals  
indicate the same element throughout the views, there is  
shown in Figure 1 a precursor stent 10, shown in Figure 1.  
As will be discussed below, precursor stent 10 is to be

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deployed within the infrarenal neck, between an abdominal aortic aneurysm and the renal arteries of a patient to assist in repairing the abdominal aortic aneurysm. The precursor stent 10 is designed to be coupled to one or more stent-grafts for directing blood flow through the aneurysm. The precursor stent 10 includes a substantially cylindrical self-expanding member 12 made from a plurality of interconnected struts. Self-expanding member 12 having two open ends, a proximal end 14, a distal end 16, and a longitudinal axis extending therebetween and an interior 18. The precursor stent 10 further includes at least two, but preferably 8 as shown in Figure 1, spaced apart longitudinal legs 20 each having proximal and distal ends 24 and 26 respectively. Preferably, there is a leg extending from each apex 11 of diamonds 13 (such diamonds being formed by the struts). The distal ends 26 of the legs are attached to the proximal end 14 of the self-expanding member 12, the legs extending proximally away from the self-expanding member. At least one, but preferably each leg includes a flange 28 adjacent its proximal end which, as is described in greater detail below, allows for the stent to be retrieved into its delivery apparatus after partial or full deployment of self-expanding member 12 so that it can be turned, or otherwise repositioned for proper alignment.--

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Please replace the paragraph beginning at page 9, line 10, with the following rewritten paragraph:

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--The self-expanding stents described herein are preferably made from superelastic Nickel Titanium alloys (Nitinol). Descriptions of medical devices which use such alloys can be found in U.S. Patents 4,665,906 issued to Jervis on May 19, 1987, and European Patent Application EP 0928606 filed on January 8, 1999, both of which are hereby incorporated herein by reference. Precursor stent 10 is preferably laser cut from a tubular piece of Nickel Titanium Alloy and thereafter treated so as to exhibit superelastic properties at body temperature. Precursor stent 10 is shown in the figures as being a diamond patterned stent, having approximately 8 diamonds, and when the stent is fully expanded the diamonds would have angles of 45-55 degrees at their distal and proximal ends. However, precursor stent 10 can take on many different patterns or configurations.--

1 Please replace the paragraph beginning at page 9, line 22, with the following rewritten paragraph:

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-- In one embodiment of precursor stent 10, shown in most of the figures but removed from Figure 1 for clarity, precursor stent 10 further includes a gasket member 30 (thereby forming a stent gasket or stent graft). This feature can be better understood by referring to Figures 2 and 3. As seen from those figures, precursor stent 10 further includes a gasket member 30. Gasket member 30 surrounds the self-expanding member 12 and can be located along the interior of self-expanding member 12, the exterior of self-expanding member 12 or both. The gasket member 30 helps impede any blood trying to flow around the

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stent grafts, described below, after they have been inserted (as shown in Figure 19) and from flowing around the precursor stent 10 itself. For this embodiment gasket member 30 is a compressible member located along both the interior and the exterior of self-expanding member 12.--

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Please replace the paragraph beginning at page 10, line 16, with the following rewritten paragraph:

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--This ability of the tissue from the artery wall to incorporate the open-pore foam structure has been termed by assignee as "Biofusion". This tissue incorporation effect can best seen by referring to the photographs of Figures 21 and 22. Figure 22 shows histological photographs of connective tissue infiltrating and healing into the gasket member 30 upon a 1 month follow-up of a device implanted into a target vessel. This ability of the tissue to heal into the foam creates a long term stable biological interface which, upon about six weeks after implantation, cannot be separated from the tissue without tearing the foam material. The "Biofusion" effect has many advantages. It has the potential to obviate late endo-leakage by preventing areas of non-organized clot from being displaced or recanalized. It is also believed that "Biofusion" creates a connective tissue collar around the gasket that would prevent the aortic neck from dilating over time. Restriction of neck dilation avoids endoleakage paths and implant migration that can be caused by an insufficient fit with the aorta. The use of such above described foams on stent grafts is not limited to abdominal aortic aneurysm

96 repair, but could be applied in many stent graft applications such as other aneurysm repair and vessel malformation and occlusion.--

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Please replace the paragraph beginning at page 11, line 1, with the following paragraph:

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97 --The foams described above are preferably highly compressible, so as to keep the crimped profile low for better delivery. In addition, it is preferable that the gasket member be substantially impervious to the flow of blood, at least when in a partially compressed state. When used throughout for the present invention, materials which are substantially impervious to the flow of blood include materials which become substantially impervious to the flow of blood after being saturated with blood. When the stent tubes and graft members, described below, are inserted and expanded within the gasket 30, the gasket 30 will compress. In this state, the gasket should be substantially impervious to blood so as to prevent blood from flowing through the interior 18 of self-expanding member 12 and into the aneurysm. Gasket 30 can be attached to self-expanding member 12 by any number of means including polyurethane glue, a plurality of conventional sutures of polypropylene, DACRON®, or any other suitable material and attached thereto. Other methods of attaching gasket 30 to self-expanding member 12 include adhesives, ultrasonic welding, mechanical interference fit and staples.--

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Please replace the paragraph beginning at page 11, line 16, with the following rewritten paragraph:

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48 --As seen from Figure 2, precursor stent 10 preferably includes a number of radiopaque markers 15. As shown, markers 15 are coils of radiopaque metal, wrapped around the struts of the precursor stent. The markers are positioned along the stent so that the physician can better know the exact position of the stent during deployment when viewed under fluoroscopy. Markers 15 are preferably made from 0.010" diameter tantalum (Ta) wire wrapped tightly around the struts. Three markers are used; two near the distal end of the device, and one proximal thereto. The distal two are 180° apart, and the proximal one is equally spaced between the distal two when viewed from a rotation where the top two are spaced as far apart as possible. This proximal marker then aids proper rotational positioning of the device. Specifically, one of the distal markers is 5 mm long and is adjacent to the aperture 34 in the gasket; the other is 2 mm long and is adjacent to the hole 36. Since hole 36 should be placed adjacent to the right side of the aneurysm, as shown in figure 19, the small distal marker should be placed on the right side; the proximal marker (also 2 mm long) should appear fluoroscopically to be midway between the upper two markers.--

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Please replace the paragraph beginning at page 12, line 1, with the following rewritten paragraph:

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--As seen from figures 2 and 3, the precursor stent further includes an occlusive member 32 attached to self-expanding member 12. The occlusive member covers at least a portion of the interior of the self-expanding member. The occlusive member covers the interior of self-expanding member 12 in such a way that a lumen 5 of the expandable member which provides passageway from its proximal end 14 to its distal 16 is at least partially blocked. Occlusive member 32 further includes two openings 34 and 36 extending therethrough. Opening 34 is relatively small and is designed to receive a guidewire, wherein such guidewire helps deliver precursor stent 10 to the target site. Opening 36 is relatively large, and is designed to receive another guidewire having a loaded stent graft proximal thereto. As will be explained below, the occlusive member helps to ensure proper side by side placement of the two stent-grafts.--

Please replace the paragraph beginning at page 12, line 13, with the following rewritten paragraph:

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--Precursor stent 10 acts to temporarily scaffold the gasket member within the body, until the stent-grafts are deployed (see figure 19). Shown in figure 4 is a preferred embodiment of a stent 40 for use in a stent-graft in accordance with the present invention. Stent 40 is made from a plurality of interconnected struts 44, and has an interior surface 43A and an exterior surface 43B (shown in figure 15). Figure 4 shows stent 40 in its fully deployed, un-crimped state. As will be appreciated by those skilled

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in the art, stent 40 should be crimped to a smaller diameter prior to insertion into a patient. Stent 40 is preferably made from superelastic Nitinol, and have enough outward force to stay within the body, without the use of the precursor stent 10. Stent 40 is preferably made from a single tube of Nitinol, having the following features laser cut therein. Stent 40 has a number of hoops 42 comprising a number of struts 44 making a diamond shape configuration, wherein each hoop preferably has 9 diamonds. Stent 40 further includes a number of sinusoidal rings 50 for connecting adjacent hoops to one another. The sinusoidal rings are made from a number of alternating struts 52, wherein each ring preferably has 54 struts. As will be explained in detail below in connection with the discussion of figures 9-14, stent 40 includes a distal attachment means 54 and a proximal attachment means 56.--

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Please replace the paragraph beginning at page 12, line 31, with the following rewritten paragraph:

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911  
--Stent 40 has a proximal hoop 48 and a distal hoop 46, also referred to as anchors. The proximal hoop is flared, and is exposed after the graft has been attached thereto. The diamond pattern for the anchors, as well as the other hoops, provide the hoops with radial and longitudinal stiffness. The longitudinal strength provides for better mechanical fixation of stent 40 to a graft (described below). The radial strength provides the distal hoop 46 with better attachment and sealing to stent gasket or precursor stent 10, and provides the proximal hoop 48 with



Q11  
better fixation and sealing to the arterial wall. In one preferred embodiment, the proximal and distal hoops have greater radial and longitudinal strength than the hoops therebetween. This creates a stent-graft having stiff ends for anchoring, but a more flexible body for navigation through the vasculature. The stiffer ends can be accomplished by changing the dimensions of the struts for the end hoops, or by varying the heat treatment of the end hoops during manufacture. The rings allow the stent to bend more easily, and generally provide for more flexibility when the stent is being delivered through a tortuous vessel. When a non-compliant graft is attached to stent 40, the strength of the diamond hoops scaffolds any graft folding into the blood flow lumen, while maintaining a tight kink radius.--

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Please replace the paragraph beginning at page 14, line 27, with the following rewritten paragraph:

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Q12  
--Figure 9 shows an up-close view of distal attachment means 54 of stent 40. Distal hoop 46 of stent 40 has a plurality of attachment tabs 82 extending therefrom which are formed from the joining together of two struts 44(a) and 44(b). Attachment means 54 comprises two apertures 84 (first aperture) and 86 (second aperture) extending therethrough. As seen from figure 10, graft 60 also preferably includes two apertures 74 and 76 (which can be initially created during the attachment process) which are coextensive with apertures 84 and 86 when graft 60 is placed over stent 40 for attachment. Finally, attachment

Q12 means 54 includes a staple 90 having a crown 92 and attachment legs 94 (first leg) and 96 (second leg) extending therefrom. Attachment leg 96 extends through apertures 76 and then aperture 86. Simultaneously, leg 94 bends around notch 85, but it does not penetrate graft 60 like leg 96. Thereafter, attachment leg 94 and 96 are bent back through apertures 84 and 74 and in towards crown 92, so as to attach the distal end of the graft to the distal end of the stent as shown in Figure 11. Legs 94 and 96 make contact with crown 92 after attachment. Preferably, there are six staples at the distal end.--

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Please replace the paragraph beginning at page 15, line 10, with the following rewritten paragraph:

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Q13 --Figure 12 shows an up-close view of proximal attachment means 56 of stent 40. Proximal hoop 48 of stent 40 has a plurality of members 110 occurring at the joining of four struts 44(c)-44(f). Attachment means 56 comprises three apertures 112 (first aperture), 114 (middle aperture) and 116 (second aperture) extending therethrough. As seen from figure 13, graft 60 also preferably includes three apertures 121, 123 and 125 (which can be initially made during the attachment process by puncturing therethrough with a staple) which are coextensive with apertures 112, 114 and 116 when graft 60 is placed over stent 40 for attachment. Finally, attachment means 56 includes a staple 120 having a crown 122 and legs 124 (first leg) and 126 (second leg) extending therefrom. Legs 124 and 126 extend through apertures 112 and 116 and then through apertures

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121 and 125 respectively. Thereafter, legs 124 and 126 are bent back through apertures 124 and 114 and in towards crown 122, so as to attach the proximal end of the graft to the proximal end of the stent as shown in figure 14. Legs 124 and 126 make contact with crown 122 after attachment. Preferably, there are three staples at the proximal end.--

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Please replace the paragraph beginning at page 15, line 26, with the following paragraph:

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--The above staple aperture design has many advantages for attaching a stent to a graft. Because the legs of the staple are folded around and imbedded within a pocket or the like, any risk of puncturing an inflation balloon is minimized. In addition, the structural integrity of the stent-graft is believed to be increased in that these staples should more securely attach the graft to the stent compared to prior art designs which use suture or adhesives to attach the graft to the stent. Staples 90 and 120, illustrated in Figure 8, can be made from any number of materials known in the art, including tantalum alloys, platinum alloys or stainless steel, such as 316 LVM stainless steel. The staples may take on other configurations and shapes, and can be coated for lubricity purposes. Having the staples made from a radiopaque material helps the physician in accurately deploying the device.--

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Please replace the paragraph beginning at page 16, line 5, with the following rewritten paragraph:

Q15  
--Another feature of stent-graft 80, illustrated in Figure 8, can be better understood by referring to its delivery apparatus 130 shown in Figure 15. Apparatus 130 is very similar to other self-expanding delivery apparatus described in the above incorporated references. Apparatus 130 includes an outer sheath 132 which is essentially an elongated tubular member, similar to ordinary guiding catheters which are well known to those of ordinary skill in the art. An example of a particularly preferred outer sheath is described in commonly assigned U.S. Patent 6,019,778 issued on February 1, 2000, which is hereby incorporated herein by reference. Sheath 132 has a distal end 134 and a proximal end (not shown). Apparatus 130 also includes an inner shaft 140 located coaxially within the outer sheath 132 prior to deployment. The inner shaft has a distal end 142 and a proximal end (not shown). The distal end 142 of the shaft has at least two grooves 144 disposed thereon. Stent 40 preferably has a number of flanges 41 disposed at its proximal end. The flanges on the stent are set within the grooves of the inner shaft, thereby releasably attaching the stent to the inner shaft. The delivery system for precursor stent 10 is also similar, having an outer sheath and an inner shaft wherein the shaft has grooves to receive flanges 28 of precursor stent 10.--

Please replace the paragraph beginning at page 16, line 23, with the following rewritten paragraph:

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--The advantages of flanges 41 on stent 40 and flanges 28 on precursor stent 10 and the grooves on the inner shafts of their delivery system is that they may allow for partial deployment of the stents and recapture within the delivery apparatus if the physician is not pleased with the position of the stent. The present invention allows the physician to partially deploy one of the stents (precursor stent 10 or stent-graft 80) while the flanges remain within the sheath. The flange groove combination allows the physician to "pull" the stent back into the delivery device if the placement is not optimal.--

Please replace the paragraph beginning at page 16, line 31, with the following rewritten paragraph:

9/17

--The advantages of flanges 28 on precursor stent 10 and the grooves on the inner shafts of their delivery system can best be described by referring to figures 23-25. Figure 23 shows an exemplary embodiment of the delivery apparatus 130 for stent gasket or precursor stent 10. Apparatus 130 is very similar to other self-expanding delivery apparatus described in the above incorporated references. Apparatus 130 includes an outer sheath 132 which is essentially an elongated tubular member, similar to ordinary guiding catheters which are well known to those of ordinary skill in the art. An example of a particularly preferred outer sheath is described in commonly assigned U.S. Patent 6,019,778 issued on February 1, 2000, which is hereby incorporated herein by reference. Apparatus 130 also includes an inner shaft 140 located coaxially within the

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outer sheath 132 prior to deployment. Inner shaft 140 includes a number of grooves 144. As seen from Figure 24, this arrangement allows for partial deployment of precursor stent 10 and recapture within the delivery apparatus if the physician is not pleased with the initial position of the stent. The present invention allows the physician to partially deploy precursor stent 10 while the flanges remain within the sheath. The flange groove combination allows the physician to "pull" the stent back into the delivery device if the placement is not optimal.--

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Please replace the paragraph beginning at page 17, line 18, with the following rewritten paragraph:

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918  
--In order to prevent the physician from prematurely completely deploying the precursor stent 10, a releasable stop 150 is preferably placed on the inner shaft. The stop could be a ring having a greater diameter than the sheath, so that as the sheath is pulled proximally along the inner shaft it hits the stop, and prevents full deployment of the entire precursor stent 10. The stop is preferably releasably attached to the inner member so that it can be released from its engagement with the inner shaft to allow the outer member to slide back enough to fully deploy the entire precursor stent 10 within the body.--

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Please replace the paragraph beginning at page 17, line 24, with the following rewritten paragraph:

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--Figures 16-18 generally show how the above described invention is deployed within the body. Prior to what is shown in Figure 16, the physician would first insert the precursor stent 10, having the gasket member attached thereto, into the body with the aid of guidewire 200, which remains in the body after deployment. The stent gasket or precursor stent 10 is delivered through one of the patient's femoral arteries and into a first iliac artery 1 and deployed within the infrarenal neck 3. Thereafter, the delivery device for the precursor stent 10 is removed, without removing guidewire 200, and another guidewire 202 is inserted through the other femoral artery and into the other iliac artery 2. Because the size of opening 36 in occlusive member 32 is relatively large, the physician can only maneuver guidewire 202 therethrough. Thereafter stent-graft delivery apparatus 130a and 130(b) are inserted into femoral arteries and into the iliac arteries 1 and 2 by sliding them over guidewires 200 and 202, and accurately delivering them to the target site. Thereafter, both stent-grafts 80(a) and 80(b) are either separately or simultaneously deployed within the body. Ultimately the distal ends of the stent grafts reside level with each other, just below the renal arteries, and some distance above the distal end of the stent gasket. The bodies of the stent grafts pass through the stent gasket and through the aneurysm sac.--

Please replace the following paragraph beginning at page 18, line 9, with the following rewritten paragraph:

Q20 --After properly delivery, precursor stent 10 and stent-grafts 80(a) and 80(b) should appear as they do in figure 19. Precursor stent 10 along with its attached gasket member 30 are firmly secured within the infrarenal neck 3. The outward force of the stent-grafts 80 on the precursor stent 10 help to secure the device within the body. The proximal ends of the stent-grafts are firmly attached to the iliac arteries 1 and 2. Thereafter blood will flow from the abdominal aorta 302 down into and through stent-grafts 80(a) and 80(b) and into iliac arteries 1 and 2, thereby bypassing the aneurysmal sack 304. If all the components are placed accurately, distal end of the device should appear as it does in Figure 20.--

Please replace the paragraph beginning at page 18, line 19, with the following paragraph:

Q21 --In order to prevent the physician from prematurely completely deploying the precursor stent 10, a releasable stop is preferably placed on the inner shaft. The stop could be a ring having a greater diameter than the outer member, so that as the outer member is pulled proximally along the inner shaft it hits the stop, and prevents full deployment of the entire precursor stent 10. The stop is preferably releasably attached to the inner member, by threads, snap fit or the like, so that it can be released from its engagement with the inner shaft to allow the outer member to slide back enough to fully deploy the entire precursor stent 10 within the body.